Review Programme: ECHA takes action

Biocides Day

29 October 2019

Hugues Kenigswald
European Chemicals Agency

Overview

- Status and trend
- What has been done?
- How to go further?

Overview

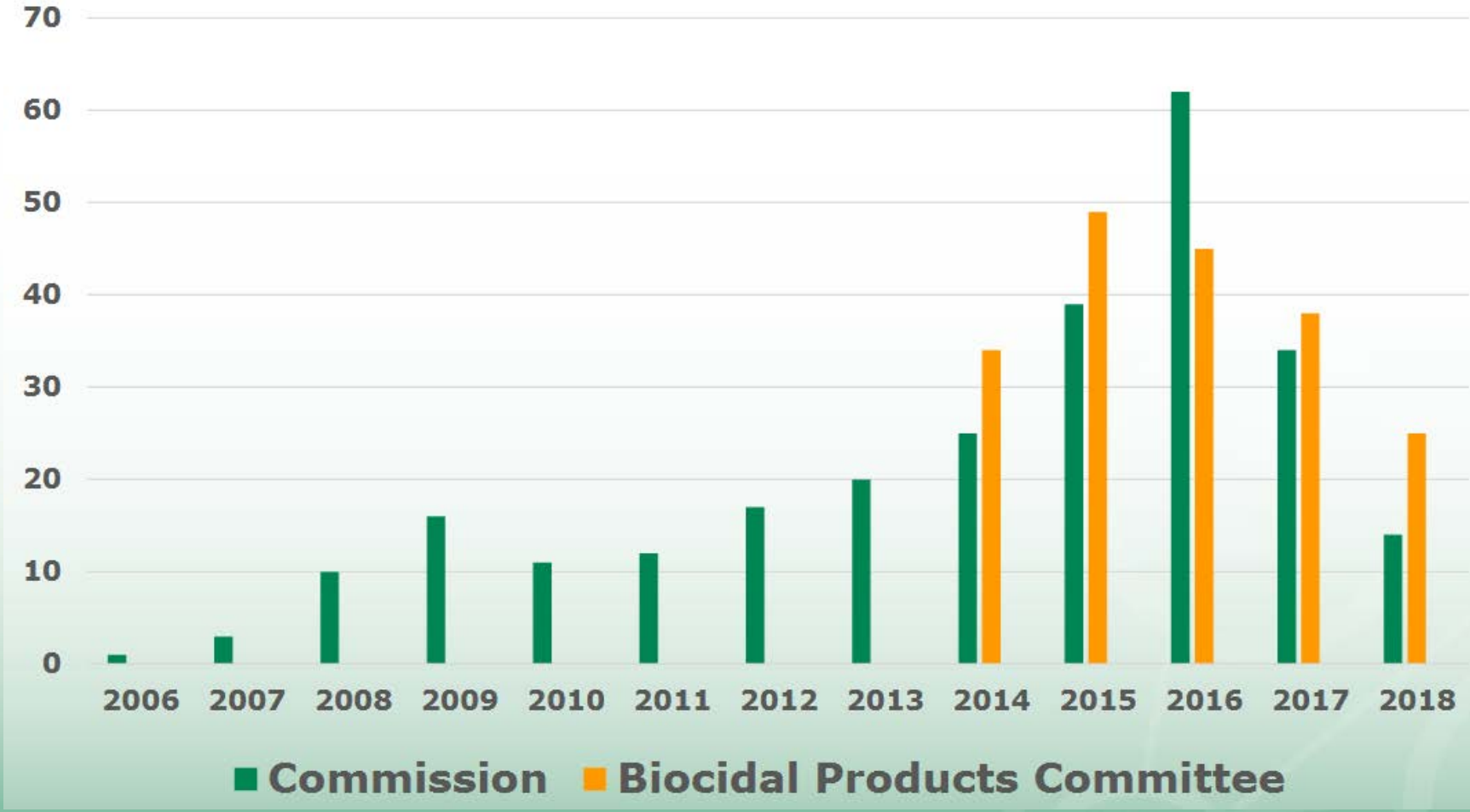
- Status and trend
- What has been done?
- How to go further?

Status and perspective

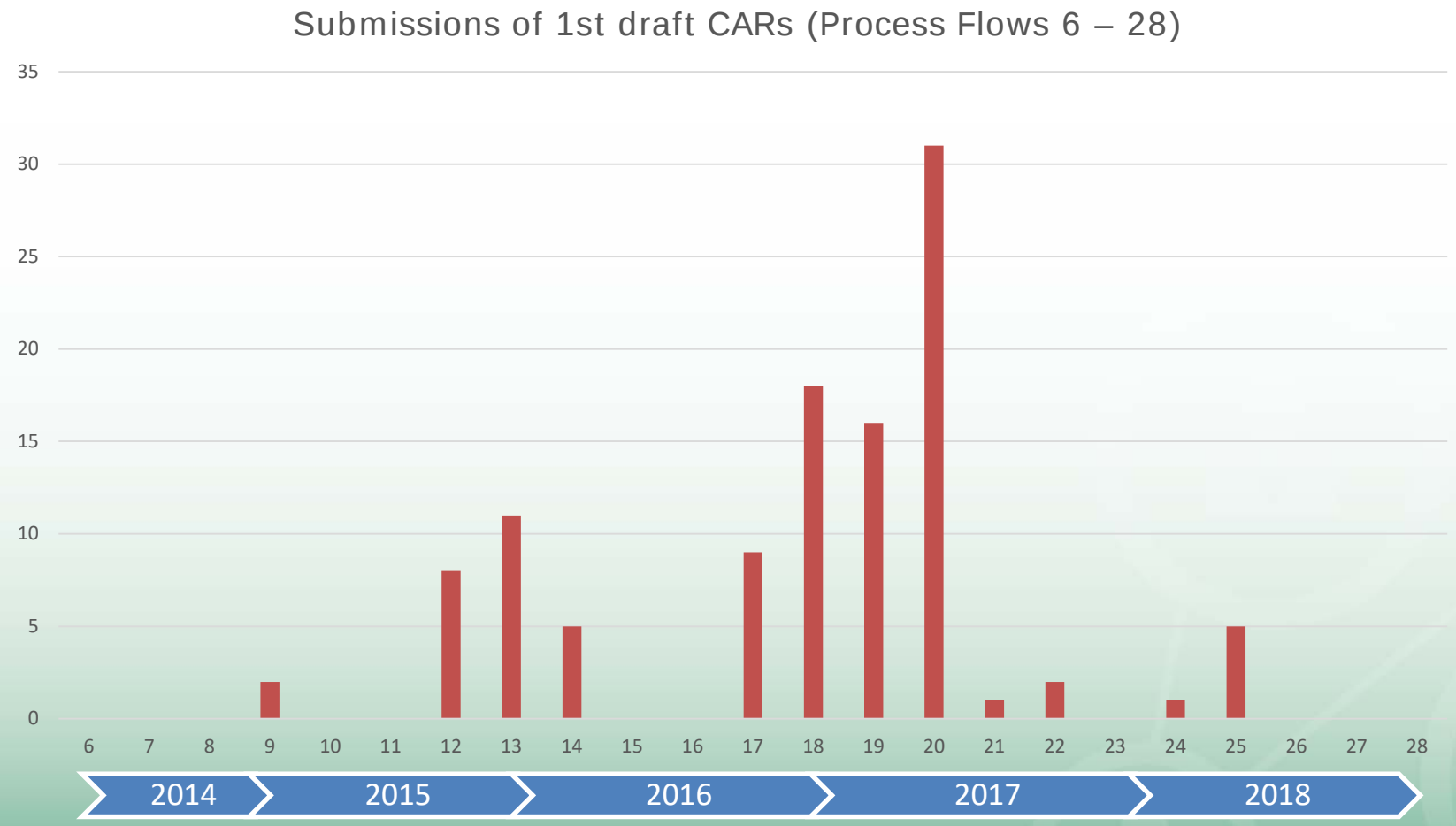
- 1/3 finalised after 15 years
- 5 years remaining

  → would require more than 80 opinions per year

Trend – active substance approvals



Trend – draft CA reports (CARs)



Overview

- Status and trend
- What has been done?
- How to go further?

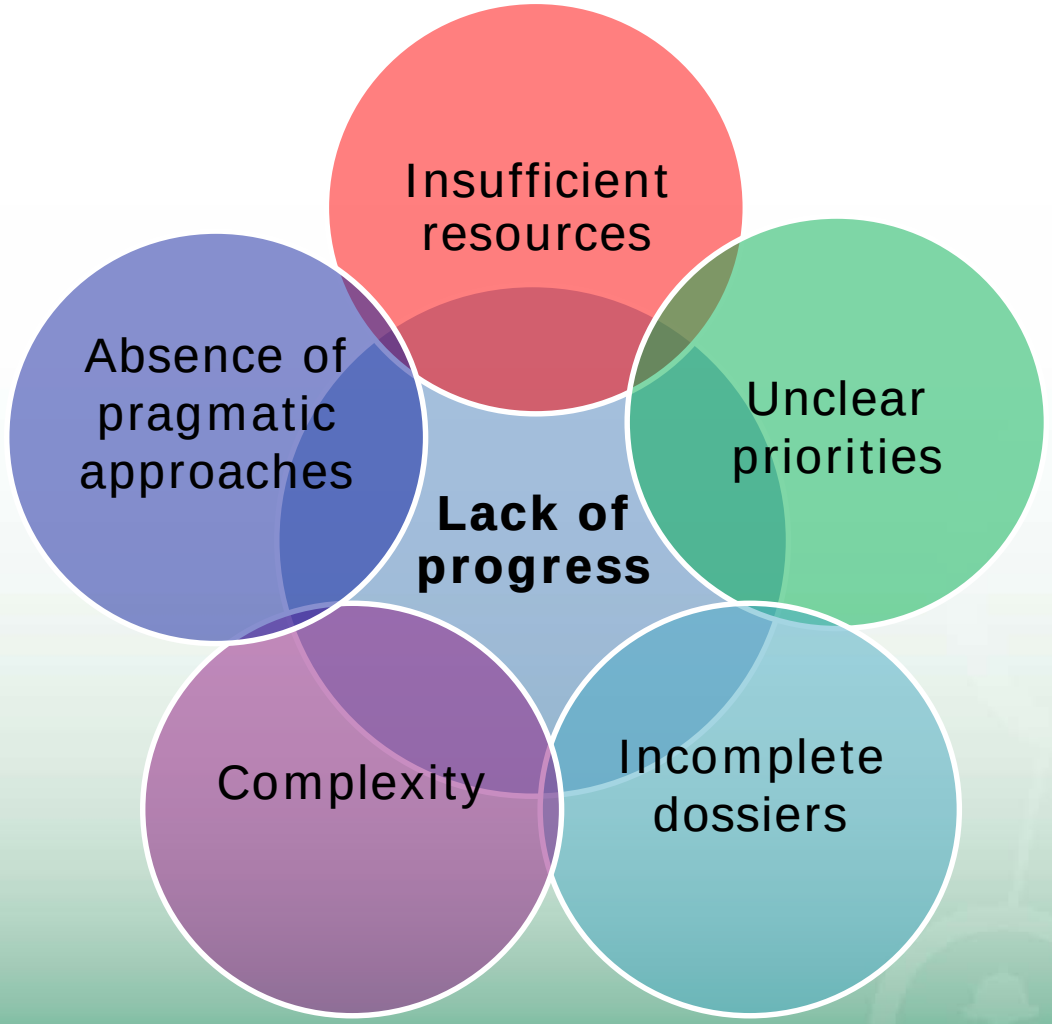
Survey « Grip on the Review Programme »

- Objectives:
  - Know the status of each Review Programme dossier under evaluation
  - Identify causes preventing progress
  - Develop cooperation during the evaluation phase
- April–September 2018
- Main outcomes:
  - Identification of the most important issues
  - Identification of common issues

Active substance workshop 2019

- Objectives:
  - Identify causes for the slow down of the Review Programme
  - Find solutions and improve the process
- Important participation
- Identification of main causes and pragmatic solutions
- Start of concerted action

Causes for lack of progresses



Prioritisation of dossiers and support

Issues to address: Insufficient resources in MSs | Unclear priorities

Actions:

1. Clarify the priorities: backlog + Review programme priority lists
2. Direct support by ECHA
   - e.g. Diamine PT8: exposure and risk assessment

Support for ED assessment

Issue to address: Insufficient resources in MSs

Actions:

1. Practical recommendations to support applicants and eCAs in preparing the ED assessment.
   Finalisation foreseen Q4 2019 – Q1 2020
2. ED expert group: advice by the expert group
   - to date 12 dossiers (16 substances) discussed
3. Direct support by ECHA for ED assessment
   - support provided for 12 dossiers (8 MS)

Relationship with applicants

Issue to address: Incomplete dossiers

Actions:

1. Procedural guidance to request additional information and dealing with applicant not submitting the requested information
2. Related letter templates

Peer review streamlining

Issue to address: Complexity

Actions:

1. New RCOM template: includes indication of the impact of the comment and a justification
2. Early working groups: document listing items always to be discussed at early working groups
3. Ad hoc follow up: document clarifying the triggering
4. Reopening agreements: rules for reopening TM/WG agreements

Information clearer and easier to find

Issues to address: Complexity

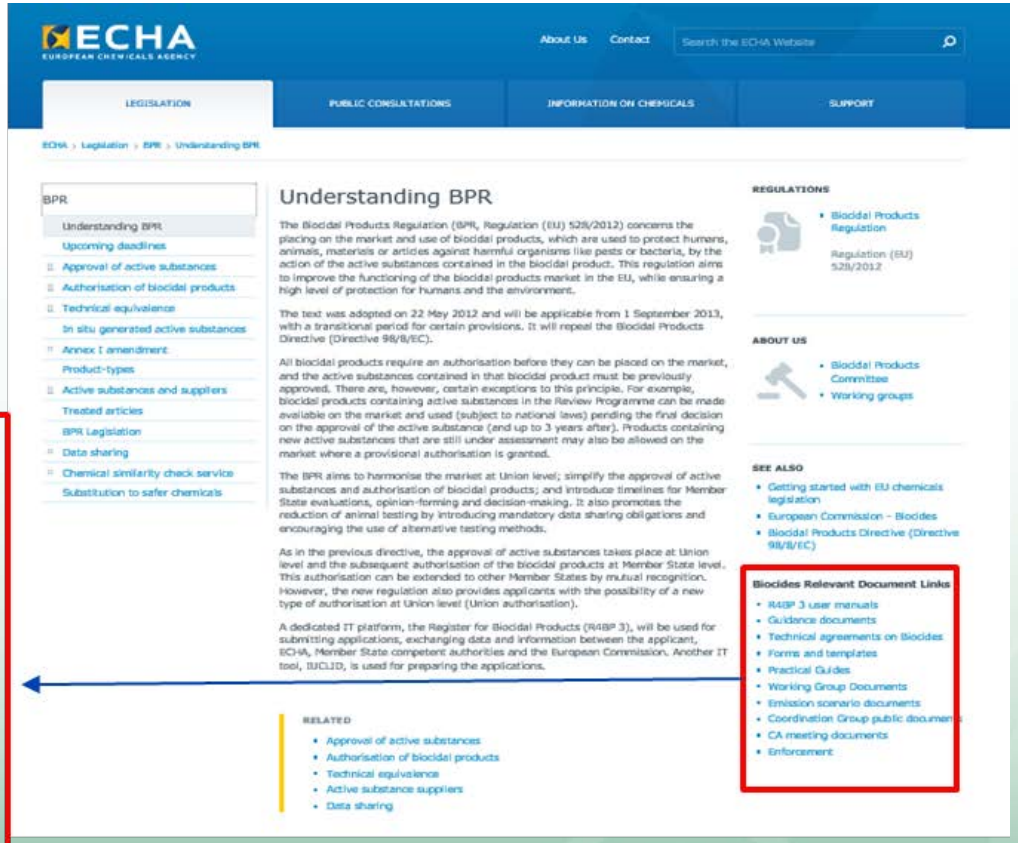
Actions:

1. Links to key documents on ECHA's website
2. Mapping and clarification of quasi guidance documents (ongoing)
3. Improving the format of TAB (ongoing)

Improving the access to information

Biocides Relevant Document Links

- R4BP 3 user manuals
- Guidance documents
- Technical agreements on Biocides
- Forms and templates
- Practical Guides
- Working Group Documents
- Emission scenario documents
- Coordination Group public documents
- CA meeting documents
- Enforcement



Interface CLP – BPR

Issues to address: Complexity | Insufficient resources in MSs

Actions:

1. Improved CAR–CLH template
2. Revitalise joint MSCAs task force CLH–biocides

Harmonised assessment of confidentiality claims

Issues to address: Complexity

Actions:

- Recommendations for assessing confidentiality claims for CARs (under preparation), finalisation foreseen Q4 2019 – Q1 2020

Overview

- Status and trend
- What has been done?
- How to go further?

Making the approach sustainable

- Need for coordinated action
- Need for MSCAs commitment and cooperation
- ECHA's resources alone are not sufficient
- Policy and even legislation may need to be re-discussed

→ **Action plan for CA meeting agreement**

Addressing resource needs

- Support and coordination by ECHA
- Support by other MSCAs
- Support by external experts
- MSCAs resources building
- Grouping active substances to reduce overall resource needs

Improving effectiveness and efficiency

- Harmonise assessments
- Streamline peer review
- Limit revision of the assessment to formal review (Article 15) and renewal
- Optimise the ED assessment strategy for substances already meeting exclusion criteria
- Improve CLP–BPR interface

Thank you

hugues.kenigswald(at)echa.europa.eu

Follow our news

News: echa.europa.eu/subscribe
Twitter: EU_ECHA
Facebook: EUECHA
YouTube: Euchemicals
LinkedIn: European Chemicals Agency